

In taking up an amended application for action, the examiner should note in every letter all the requirements outstanding against the application. Every point in the prior action of an examiner which is still applicable must be repeated or referred to, to prevent the implied waiver of the *requirement*.

37 C.F.R. § 1.113 requires, in part, that "[i]n making [a] final rejection, the examiner shall repeat or state all grounds of rejection then considered applicable to the claims in the application, clearly stating the reasons in support thereof."

In the first Office Action a double patenting rejection was posed by the Patent Office. Applicants traversed this rejection. However, the instant Office Action makes no statement as to whether or not this rejection is withdrawn or maintained. Because the Office Action is silent, Applicants must assume that the rejection has been withdrawn. See, MPEP § 707 and 37 C.F.R. § 1.113.

In the previous Office Action Claims 1-20 were rejected under 35 U.S.C. § 102 as allegedly being anticipated by *Cope et al.* '872. Applicants traversed this rejection. The final Office Action fails to state that this rejection has been withdrawn or maintained. Accordingly, Applicants assume that the rejection was withdrawn. See, MPEP § 707 and 37 C.F.R. § 1.113.

Claims 1-20 also were rejected in the previous Office Action under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,714, 472 (*Gray et al.*). Applicants traversed this rejection in their previous Amendment. The final Office Action is silent as to this rejection. Accordingly, Applicants assume this rejection has been withdrawn. See, MPEP § 707 and 37 C.F.R. § 1.113.

Claims 1-3, 5, and 7-16 were rejected in the previous Office Action under 35 U.S.C. § 102 as being anticipated by *Cope et al.* '782. Applicants traversed this rejection and the final Office Action is silent with respect to this rejection. Therefore, Applicants respectfully submit that similar to the previous rejections that are noted above, that this rejection has also been withdrawn due to implied waiver. See, MPEP § 707 and 37 C.F.R. § 1.113.

In the previous Office Action Claim 4 was rejected under 35 U.S.C. § 112. Applicants amended Claim 4 to overcome this rejection. Once again the Office Action is silent as to whether or not this rejection is withdrawn in view of the Amendment. Accordingly, Applicants must assume that it has been withdrawn. See, MPEP § 707 and 37 C.F.R. § 1.113.

In view of the foregoing, Applicants believe that the current status of the application is as follows: Claims 1-7, 9-13, 15, and 17-20 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,504,072 (*Schmidl et al.*); Claims 1-20 stand rejected as being obvious in view of a combination of nine references; and Claims 1-20 are rejected as being obvious in a new rejection based on two references.

As noted above, the only § 102 rejection discussed in the final Office Action is of Claims 1-7, 9-13, 15, and 17-20 under 35 U.S.C. § 102 as being anticipated by *Schmidl et al.* Applicants respectfully submit that this rejection is clearly not proper as a matter of law. In fact, the final Office Action tacitly admits that the rejection is not proper.

Under U.S. law, an anticipation rejection is an objective determination. "For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in the single reference." *In re Bond*, 910 F.2d 831, 15 USPQ 2d 1566 (Fed.Cir. 1990) (emphasis added). "There must be no difference between the claimed invention and the referenced disclosure." *Scripps Clinic & Research Foundation v. Genetech, Inc.*, 927 F.2d 1565, 18 USPQ 2d 1001 (Fed.Cir. 1991) (emphasis added). "For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art." *Motorola, Inc. v. Interdigital Technology Corp.*, 121 F.3d 1461, 43 USPQ 2d 1481 (Fed.Cir. 1997) (emphasis added).

Using this test, it is clear that the anticipation rejection is not proper. Each of the independent claims specifically requires that the enteral composition have a caloric density of at least 1.4 kcal/ml. *Schmidl*, as the Patent Office admits in the final rejection, "possesses a caloric density of 1 kcal/ml." 1 is not the same as 1.4; 1 kcal/ml is not the same as at least 1.4 kcal/ml. Thus, the literal identity test that is required for an anticipation rejection is not met.

Applicants respectfully submit that the Office Action itself demonstrates that the correct test of anticipation is not being applied. In this regard, the Examiner in attempting to justify the rejection states "when a patent contains a range that varies from the parameter in the prior art, 'the Applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range'." This statement is inapposite with respect to the instant anticipation rejection. The Examiner has cited case law that deals either with obviousness rejections or where the prior art includes ranges that overlap with the claim in issue. In the present situation the *Schmidl* disclosure falls outside the claims. Thus an anticipation rejection is not proper, whether or not criticality is shown.

Moreover, each of the independent claims requires that the protein source "consists essentially of" partially hydrolyzed protein. *Schmidl* teaches that a number of proteins can be utilized including intact proteins along with protein hydrolyzate. "Consisting essentially of" is a transition phrase used in patent claims to limit the claim and to signal a partially open claim. *PPG Industries v. Guardian Industries Corp.*, 156 F.3d 1351, 48 USPQ 2d 1351 (Fed.Cir. 1998). This phrase excludes from the claim ingredients that materially affect the basic and novel characteristics of the claimed invention. *Atlas Powder Co. v. E.I. Du Pont de Nemours and Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed.Cir. 1984). Accordingly, a protein source that includes

partially hydrolyzed proteins with intact proteins does not read on "consisting essentially of" partially hydrolyzed proteins.

Applicants respectfully submit that the anticipation rejection is not proper and should be withdrawn. To the extent that the Examiner believes that the rejection is proper, Applicants respectfully request that the Examiner confer with his supervisor to determine the proper analysis with respect to anticipation.

In the final Office Action, the Patent Office presents a new rejection. In this regard, Claims 1-20 stand rejected under 35 U.S.C. § 103 as being unpatentable over *Schmidl* and *Gray*. This rejection is being posed for the first time by the Patent Office. Accordingly, Applicants question why the Examiner has made the Office Action final. Applicants' amendments to the claims did not necessitate the new rejection; the Office Action is silent as to this issue. Thus, the finality of the Office Action is not proper. Once again, Applicants respectfully submit that the examiner has failed to comply with the requirements of the Patent Office - in this regard, a new rejection cannot be made final unless Applicants' amendment necessitated the new rejection.

Regardless, this rejection, it is respectfully submitted, is not proper. As noted above, *Schmidl* fails to disclose or suggest the caloric density of the product which is a required element of each of the claims, or the use of protein hydrolyzate as the sole protein source, which is a claimed element of each of the independent claims. *Gray* does not remedy the deficiencies of *Schmidl*.

Moreover, *Gray* teaches away from the claimed invention by claiming a high protein content of at least 22% of the calories in the product. The claimed invention provides a product that is specifically directed to meet the nutritional needs of metabolically stressed patients without elevated protein levels or excess fluid. Unlike the claimed invention, *Gray* teaches that

the total non-protein calories per gram of nitrogen is less than or equal to 70:1. Unlike prior formulations, the claimed invention provides calorically dense nutritional support in the form of an elemental diet while at the same time providing a moderate npc/gn ratio. Thus, if anything, *Gray* teaches away from the claimed invention.

Moreover, the Office Action in and of itself fails to disclose how the combination discloses Applicants' claimed invention. In this regard, the Office Action refers Applicants to the previous Office Action as setting forth the rationale for the rejection. As noted previously, the previous Office Action does not discuss this rejection! This, in and of itself, demonstrates that the rejection is not proper and should be withdrawn.

It appears that the Office Action is also maintaining the previous obviousness rejection of Claims 1-20 in view of a combination of nine separate references. Applicants once again submit for the reasons set forth in their previous response that this obviousness rejection is clearly not proper.

The principle reference relied upon for this nine reference rejection is a Traumacal brochure. The Traumacal brochure fails to meet a large number of the claimed features. For example, the Traumacal formulation includes a higher protein content, at least 22% of the calories of the total composition, than the claimed invention. The Traumacal formulation does not teach the claimed ratio of non-protein calories per gram nitrogen. Further, the Traumacal formulation does not claim the vitamin profile. Nor does the Traumacal formulation claim the use of beta-carotene. Further, the Traumacal formulation only meets the USRDA of vitamins and minerals and 3000 kcal (200 mL). Accordingly, the primary reference fails to teach many essential features of the claimed invention.

In response, what the Examiner merely does is points to the other eight references as allegedly disclosing individual features. The Patent Office fails to answer the fundamental question: where is the motivation in the art for the modifications suggested by the Examiner. If Traumacal is the primary reference, which it was in the last rejection, the question is why would it be obvious to one skilled in the art to so modify Traumacal. What the Examiner has done, it is respectfully submitted, is merely selected individual elements from the prior art. This is not proper.

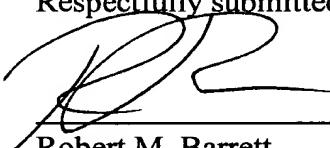
Nor, it is respectfully submitted, is the Examiner correct that the test for obviousness is simply what the combined teachings of the references would suggest to one skilled in the art. "The obviousness standard, while easy to expound, is sometimes difficult to apply." *Uniroyal Inc. v. Rudkin-Wiley Corporation*, 837 F.2d 1044 (Fed.Cir. 1988). Of course, it is axiomatic, that "obviousness may not be established using hindsight or in view of the teachings or suggestions of the inventor." *Par-Ordnance Manufacturing Inc. v. STS Importers International Inc.*, 73 F.3d 1085 (Fed.Cir. 1995). The test is not whether or not the prior art can be modified so as to realize Applicants' claimed invention. Indeed, "the mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desireability and modification." *In re Laskowski*, 871 F.2d 115 (Fed.Cir. 1989). In this regard, "there must be some reason, suggestion, or motivation found that the prior art whereby a person of ordinary skill in the field of the invention would make the combination. The knowledge can not come from the Applicants' invention itself." *In re Oetiker*, 977 F.2d 1443 (Fed.Cir. 1992).

The test is whether or not there is a motivation in the art for the combination suggested by the Patent Office. The test for obviousness is not whether or not the invention can be piece-meal reconstructed from the prior art. Unfortunately, Applicants respectfully submit, this is what

the Patent Office has done. Therefore, Applicants respectfully request that the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the rejections of the claims are improper as a matter of law and fact. Therefore, Applicants respectfully request that the Patent office reconsider these rejections and withdraw same. Further, Applicants respectfully submit that the patent application is now in condition for allowance and respectfully request that it be passed to allowance.

Respectfully submitted,



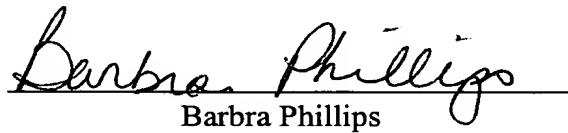
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CERTIFICATE OF HAND DELIVERY

I hereby certify that this correspondence is being hand delivered to Examiner Nutter at Group Art Unit 1711 at the United States Patent and Trademark Office, Washington, D.C. 20231 on Thursday, December 2, 1999.



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